

Notice of Allowability

Application No.

09/508,658

Examiner

Jehanne S. Sitton

Applicant(s)

KROHN ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to 10/2/2006.
2. ☒ The allowed claim(s) is/are 27, 36 and 37.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 7/06, 3/00
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____

7. ☐ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☒ Other Alignment of instant Seq ID No: 1
w/ Seq ID No: 1 of US Patent 6,951,928

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: The claims are drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 1, as well as isolated nucleic acid molecules comprising SEQ ID NO: 1 where position 905 is a T instead of a C, or where position 383 is a G instead of an A. The prior art does not teach or fairly suggest the sequence of these nucleic acid molecules. Support for the nucleotide alterations is in SEQ ID NO: 1 as well as figure 3A, B, and C, (alignment of the sequences for the sequencing results with SEQ ID NO: 1). Support for the amendments to the specification and the drawings (Figure 2) to change K42E to K83E is in Figure 3C, which contains the data for the sequencing reaction to determine the mutation at position 383 of SEQ ID NO: 1. Alignment of the nucleotides surrounding the mutant position with SEQ ID NO: 1 reveals that the designation of codon 42 was incorrect and that the correct codon is 83. Accordingly, one of skill in the art would not only recognize that the designation of codon 42 in the specification was an obvious error, but would also recognize the appropriate correction. MPEP 2163.07 II. SEQ ID NO: 1 and Figures 3A, 3B, and 3C are supported in all previous priority documents.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Request for Declaration of Interference Pursuant to 37 CFR 41.202

2. In the reply filed 10/2/2006, applications suggested that and interference be declared between instant claims 27 and 36 and claims 2-4 of US Patent 6,951,928. The remarks as well as

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the claims of the instant specification and those of the '928 patent, as well as the specification of each, have been thoroughly reviewed. However, the claims in the instant application and those of the '928 Peltonen patent fail the two way test for the following reasons. 41.203 (a) states:

"Interfering subject matter. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa."

SEQ ID NO: 1 of the instant application and SEQ ID NO: 1 of the '928 patent are not identical. An alignment is provided.

Instant SEQ ID NO: 1, the subject matter of claims 27 and 36, contains 16 nucleotides on the 5' end which are not taught or suggested by SEQ ID NO: 1 of the '928 patent, the claims of the '928 patent, nor the disclosure of the '928 patent. Therefore, (with regard to the comments regarding count 1 at pages 3-5 of the response), none of the claims of the '928 patent either anticipate or are obvious over the nucleic acid molecule of instant claim 27, that is an isolated nucleic acid molecule comprising instant SEQ ID NO: 1, or the nucleic acids in claims 36 (count 2 suggested by applicant) and 37 of the instant application. On this basis, the claims fail the two way test and an interference has not been declared.

Also of note, SEQ ID NO: 1 of the '928 patent contains 25 nucleotides on the 3' end which are not taught or suggested by instant SEQ ID NO:1, claims 27, 36, or 37, or the disclosure of the instant specification. Additionally, a mismatch occurs at position 817 (C) of instant SEQ ID NO: 1 and position 801 (T) of SEQ ID NO: 1 of the '928 patent, accordingly, the sequences of instant SEQ ID NO: 1 and SEQ ID NO: 1 of the '928 patent are not identical.

Therefore claims 27, 36, and 37 of instant application are allowed.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

1/4/07

Alignment between ~~is~~ instant Seq ID NO: 1
and Seq ID NO: 1 of 6,951,928

US-09-509-595B-1

; Sequence 1, Application US/09509595B
; Patent No. 6951928
; GENERAL INFORMATION:
; APPLICANT: MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.
; APPLICANT: NATIONAL PUBLIC HEALTH INSTITUTE
; APPLICANT: PELTONEN, Leena
; APPLICANT: AALTONEN, Johanna
; APPLICANT: BJORSES, Petra
; APPLICANT: PERHEENTUPA, Jaakko
; APPLICANT: PALOTIE, Aarno
; APPLICANT: HORELLI-KUITUNEN, Nina
; APPLICANT: YASPO, Marie-Laure
; APPLICANT: LEHRACH, Hans
; TITLE OF INVENTION: NUCLEIC ACID MOLECULE ENCODING A (POLY) PEPTIDE CO-
SEGREGATING IN MUTATED
; TITLE OF INVENTION: FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS
ECTODERMAL DYSTROPHY
; TITLE OF INVENTION: (APECED)
; FILE REFERENCE: VOSS1130
; CURRENT APPLICATION NUMBER: US/09/509,595B
; CURRENT FILING DATE: 2000-07-05
; PRIOR APPLICATION NUMBER: EP 97117154.1
; PRIOR FILING DATE: 1997-10-02
; PRIOR APPLICATION NUMBER: EP 97117398.4
; PRIOR FILING DATE: 1997-10-08
; PRIOR APPLICATION NUMBER: EP 97119810.6
; PRIOR FILING DATE: 1997-11-12
; NUMBER OF SEQ ID NOS: 30
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 1
; LENGTH: 2245
; TYPE: DNA
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: CDS
; LOCATION: (121)..(1758)
; OTHER INFORMATION:

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Query Match 99.1%; Score 2018.4; DB 3; Length 2245;
Best Local Similarity 99.9%; Pred. No. 0;
Matches 2019; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy	17	CGGGCGCACAGCCGGCGCGGAGGCCCCACAGCCCCGCCGGGACCCGAGGCCAAGCGAGGG	76
Db	1	CGGGCGCACAGCCGGCGCGGAGGCCCCACAGCCCCGCCGGGACCCGAGGCCAAGCGAGGG	60
Qy	77	GCTGCCAGTGTCCCGGGACCCACCGCGTCCGCCCCAGCCCCGGGTCCCCGCGCCCACCCC	136
Db	61	GCTGCCAGTGTCCCGGGACCCACCGCGTCCGCCCCAGCCCCGGGTCCCCGCGCCCACCCC	120
Qy	137	ATGGCGACGGACGCGGCGCTACGCCGGCTTCTGAGGCTGCACCGCACGGAGATCGCGGTG	196
Db	121	ATGGCGACGGACGCGGCGCTACGCCGGCTTCTGAGGCTGCACCGCACGGAGATCGCGGTG	180
Qy	197	GCCGTGGACAGCGCCTTCCCACTGCTGCACGCGCTGGCTGACCACGACGTGGTCCCCGAG	256

Db	181	 GCCGTGGACAGCGCCTTCCCACTGCTGCACGCGCTGGCTGACCACGACGTGGTCCCCGAG	240
Qy	257	GACAAGTTTCAGGAGACGCTTCATCTGAAGGAAAAGGAGGGCTGCCCCCAGGCCTTCCAC	316
Db	241	 GACAAGTTTCAGGAGACGCTTCATCTGAAGGAAAAGGAGGGCTGCCCCCAGGCCTTCCAC	300
Qy	317	GCCCTCCTGTCTGGCTGCTGACCCAGGACTCCACAGCCATCCTGGACTTCTGGAGGGTG	376
Db	301	 GCCCTCCTGTCTGGCTGCTGACCCAGGACTCCACAGCCATCCTGGACTTCTGGAGGGTG	360
Qy	377	CTGTTCAAGGACTACAACCTGGAGCGCTATGGCCGGCTGCAGCCCATCCTGGACAGCTTC	436
Db	361	 CTGTTCAAGGACTACAACCTGGAGCGCTATGGCCGGCTGCAGCCCATCCTGGACAGCTTC	420
Qy	437	CCCAAAGATGTGGACCTCAGCCAGCCCCGGAAGGGGAGGAAGCCCCCGGCCGTCCCCAAG	496
Db	421	 CCCAAAGATGTGGACCTCAGCCAGCCCCGGAAGGGGAGGAAGCCCCCGGCCGTCCCCAAG	480
Qy	497	GCTTTGGTACCGCCACCCAGACTCCCCACCAAGAGGAAGGCCTCAGAAGAGGCTCGAGCT	556
Db	481	 GCTTTGGTACCGCCACCCAGACTCCCCACCAAGAGGAAGGCCTCAGAAGAGGCTCGAGCT	540
Qy	557	GCCGCGCCAGCAGCCCTGACTCCAAGGGGCACCGCCAGCCCAGGCTCTCAACTGAAGGCC	616
Db	541	 GCCGCGCCAGCAGCCCTGACTCCAAGGGGCACCGCCAGCCCAGGCTCTCAACTGAAGGCC	600
Qy	617	AAGCCCCCAAGAAGCCGGAGAGCAGCGCAGAGCAGCAGCGCCTTCCACTCGGGAACGGG	676
Db	601	 AAGCCCCCAAGAAGCCGGAGAGCAGCGCAGAGCAGCAGCAGCGCCTTCCACTCGGGAACGGG	660
Qy	677	ATTAGACCATGTCAGCTTCAGTCCAGAGAGCTGTGGCCATGTCTCCGGGGACGTCCCG	736
Db	661	 ATTAGACCATGTCAGCTTCAGTCCAGAGAGCTGTGGCCATGTCTCCGGGGACGTCCCG	720
Qy	737	GGAGCCCAGGGGCGGTGGAGGGGATCCTCATCCAGCAGGTGTTTGAGTCAGGCGGCTCC	796
Db	721	 GGAGCCCAGGGGCGGTGGAGGGGATCCTCATCCAGCAGGTGTTTGAGTCAGGCGGCTCC	780
Qy	797	AAGAAGTGCATCCAGGTTGGCGGGGAGTTCACACTCCCAGCAAGTTCGAAGACTCCGGC	856
Db	781	 AAGAAGTGCATCCAGGTTGGTGGGGAGTTCACACTCCCAGCAAGTTCGAAGACTCCGGC	840
Qy	857	AGTGGGAAGAACAAGGCCCGCAGCAGCAGTGGCCCGAAGCCTCTGGTTCGAGCCAAGGGA	916
Db	841	 AGTGGGAAGAACAAGGCCCGCAGCAGCAGTGGCCCGAAGCCTCTGGTTCGAGCCAAGGGA	900
Qy	917	GCCCAGGGCGCTGCCCCCGGTGGAGGTGAGGCTAGGCTGGGCCAGCAGGGCAGCGTTCCC	976
Db	901	 GCCCAGGGCGCTGCCCCCGGTGGAGGTGAGGCTAGGCTGGGCCAGCAGGGCAGCGTTCCC	960
Qy	977	GCCCCCTCTGGCCCTCCCCAGTGACCCCCAGCTCCACCAGAAGAATGAGGACGAGTGTGCC	1036
Db	961	 GCCCCCTCTGGCCCTCCCCAGTGACCCCCAGCTCCACCAGAAGAATGAGGACGAGTGTGCC	1020
Qy	1037	GTGTGTCGGGACGGCGGGGAGCTCATCTGCTGTGACGGCTGCCCTCGGGCCTTCCACCTG	1096

Db	1021	GTGTGTCGGGACGGCGGGGAGCTCATCTGCTGTGACGGCTGCCCTCGGGCCTTCCACCTG	1080
Qy	1097	GCCTGCCTGTCCCCCTCCGCTCCGGGAGATCCCCAGTGGGACCTGGAGGTGCTCCAGCTGC	1156
Db	1081	GCCTGCCTGTCCCCCTCCGCTCCGGGAGATCCCCAGTGGGACCTGGAGGTGCTCCAGCTGC	1140
Qy	1157	CTGCAGGCAACAGTCCAGGAGGTGCAGCCCCGGGCAGAGGAGCCCCGGCCCCAGGAGCCA	1216
Db	1141	CTGCAGGCAACAGTCCAGGAGGTGCAGCCCCGGGCAGAGGAGCCCCGGCCCCAGGAGCCA	1200
Qy	1217	CCCGTGGAGACCCCGCTCCCCCGGGGCTTAGGTGGCGGGAGAGGAGGTAAGAGGTCCA	1276
Db	1201	CCCGTGGAGACCCCGCTCCCCCGGGGCTTAGGTGGCGGGAGAGGAGGTAAGAGGTCCA	1260
Qy	1277	CCTGGGGAACCCCTAGCCGGCATGGACACGACTCTTGTCTACAAGCACCTGCCGGCTCCG	1336
Db	1261	CCTGGGGAACCCCTAGCCGGCATGGACACGACTCTTGTCTACAAGCACCTGCCGGCTCCG	1320
Qy	1337	CCTTCTGCAGCCCCGCTGCCAGGGCTGGACTCCTCGGCCCTGCACCCCTACTGTGTGTG	1396
Db	1321	CCTTCTGCAGCCCCGCTGCCAGGGCTGGACTCCTCGGCCCTGCACCCCTACTGTGTGTG	1380
Qy	1397	GGTCCTGAGGGTCAGCAGAACCTGGCTCCTGGTGCGCGTTGCGGGGTGTGCGGAGATGGT	1456
Db	1381	GGTCCTGAGGGTCAGCAGAACCTGGCTCCTGGTGCGCGTTGCGGGGTGTGCGGAGATGGT	1440
Qy	1457	ACGGACGTGCTGCGGTGTACTCACTGCGCCGCTGCCTTCCACTGGCGCTGCCACTTCCCA	1516
Db	1441	ACGGACGTGCTGCGGTGTACTCACTGCGCCGCTGCCTTCCACTGGCGCTGCCACTTCCCA	1500
Qy	1517	GCCGGCACCTCCCGGGCCCGGGACGGGCCTGCGCTGCAGATCCTGCTCAGGAGACGTGACC	1576
Db	1501	GCCGGCACCTCCCGGGCCCGGGACGGGCCTGCGCTGCAGATCCTGCTCAGGAGACGTGACC	1560
Qy	1577	CCAGCCCCCTGTGGAGGGGTGCTGGCCCCCAGCCCCGCGCCTGGCCCCCTGGGCCTGCC	1636
Db	1561	CCAGCCCCCTGTGGAGGGGTGCTGGCCCCCAGCCCCGCGCCTGGCCCCCTGGGCCTGCC	1620
Qy	1637	AAGGATGACACTGCCAGTCACGAGCCCGCTCTGCACAGGGATGACCTGGAGTCCCTTCTG	1696
Db	1621	AAGGATGACACTGCCAGTCACGAGCCCGCTCTGCACAGGGATGACCTGGAGTCCCTTCTG	1680
Qy	1697	AGCGAGCACACCTTCGATGGCATCCTGCAGTGGGCCATCCAGAGCATGGCCCGTCCGGCG	1756
Db	1681	AGCGAGCACACCTTCGATGGCATCCTGCAGTGGGCCATCCAGAGCATGGCCCGTCCGGCG	1740
Qy	1757	GCCCCCTTCCCCCTCCTGACCCAGATGGCCGGGACATGCAGCTCTGATGAGAGAGTGCTG	1816
Db	1741	GCCCCCTTCCCCCTCCTGACCCAGATGGCCGGGACATGCAGCTCTGATGAGAGAGTGCTG	1800
Qy	1817	AGAAGGACACCTCCTTCCTCAGTCCTGGAAGCCGGCCGGCTGGGATCAAGAAGGGGACAG	1876
Db	1801	AGAAGGACACCTCCTTCCTCAGTCCTGGAAGCCGGCCGGCTGGGATCAAGAAGGGGACAG	1860
Qy	1877	CGCCACCTCTTGTCTAGTGCTCGGCTGTAAACAGCTCTGTGTTTCTGGGGACACCAGCCAT	1936
Db	1861	CGCCACCTCTTGTCTAGTGCTCGGCTGTAAACAGCTCTGTGTTTCTGGGGACACCAGCCAT	1920

Qy 1937 CATGTGCGCTGGAAATTAAACCCGTGCCCCACTTCTCTACTCTGGAAGTCCCCGGGAGCCTC 1996
 |||
 Db 1921 CATGTGCGCTGGAAATTAAACCCGTGCCCCACTTCTCTACTCTGGAAGTCCCCGGGAGCCTC 1980

Qy 1997 TCCTTGCGCTGGTGACCTACTAAAAATATAAAAAATTAGCTG 2036
 |||
 Db 1981 TCCTTGCGCTGGTGACCTACTAAAAATATAAAAAATTAGCTG 2020